MURRAY & ASSOCIATES

5529 Perugia Circle
San Jose, CA 95138

(408) 239-0669
Fax: (408) 239-0559

May 2, 2008

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street
Sacramento, CA 95812

RE: Request for Public Participation, Notice of Public Workshop - Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept

Dear Ms. Kammerer:

I am writing on behalf of the several clients in response to the Office of Environmental Health Hazard Assessment's ("OEHHA" or the "Agency") March 21, 2008 request for public input on the "Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept." Thank you for the opportunity to participate in the public workshop on this topic on April 18 and to provide these written comments.

The Proposal provides no benefit.

I have carefully reviewed the "Possible Regulatory Language" on beneficial nutrients (the "Proposal"), and in my opinion, the Proposal provides no obvious public health benefit – or any other benefit. At the April 18 public workshop, OEHHA indicated that the Proposal would apply to only two chemicals on the Proposition 65 list: Vitamin A and chromium. However, it became apparent at the public workshop that neither of these substances would be affected by the Proposal. In other words, the Proposal would not affect any of the chemicals on the Proposition 65 list. As such, there would be no benefit to the Proposal since it would not affect any Proposition 65 listed chemical in foods.

Vitamin A Vitamin A was listed in 1989 with a qualified listing of "Retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents. (Note: retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU.)" As you know,

the Governor's Scientific Advisory Panel chose to recommend qualifying the listing of Vitamin A because daily doses above 25,000 IU were believed to cause developmental toxicity, whereas a daily dose of 8000 IU was considered essential to a healthy pregnancy. If Vitamin A had been listed without qualification, the MADL for Vitamin A would have been less than 250 IU, far less than the amount required to maintain a healthy pregnancy.

The Proposal would have no impact on Vitamin A. The RDA is below the listing of Vitamin A. So, no warning is currently required on products that contain Vitamin A unless the amount exceeds the qualified listing. The Proposal would not exempt any exposures to Vitamin A that are not already "exempted" by the qualified listing. So, the Proposal would have no impact on Vitamin A in foods.

Chromium Chromium also does not benefit from the Proposal. Chromium appears on the Proposition 65 list as "Chromium (hexavalent compounds)." In contrast, chromium as a nutrient is trivalent, not hexavalent. So, the form of chromium in foods is not the same chromium that appears on the Proposition 65 list. So, like Vitamin A, the Proposal would have no impact on chromium in foods.

There is no current benefit of the Proposal because, to the best of my knowledge, it does not apply to any substance on the Proposition 65 list that may be found in foods.

The last time the listing of a beneficial nutrient was a potential issue was in 1989 when Vitamin A was listed. In other words, a similar issue has not occurred in nearly 20 years. Further, any potential problem presented by a listing of Vitamin A was prevented by its qualified listing. Perhaps, a better way to address the issue of Proposition 65 and beneficial nutrients, if it occurs in the future, would be to address it at the listing stage, using the qualified listing approach that was employed for Vitamin A. This would allow a listing to occur in a manner that ensures public health is protected from either too much or too little of a beneficial nutrient. And, this approach would provide OEHHA with the flexibility needed to appropriately address nutritionally beneficial substances.

The Proposal to exempt exposures to beneficial nutrients should not be tied to the Recommended Dietary Allowance (RDA) or 20% of the Upper Level (UL).

A number of problems are raised by the Proposal because it ties the "no exposure level" to the Recommended Dietary Allowance (RDA) or 20% of the Upper Level (UL). Some examples of the issues raised by the Proposal are described in this section.

The RDA is not a safety threshold. To the contrary, RDAs are amounts of selected nutrients considered necessary for all healthy individuals. RDAs set a general guideline for individuals to follow. RDAs are not amounts recommended for optimal health. Nutritionists frequently recommend exceeding the RDAs for optimal health. More importantly, RDAs are not amounts that should not be exceeded for safety reasons. The Proposal presumes that it is unsafe or undesirable for the public to have exposures to beneficial nutrients in amounts exceeding the RDA.

Not all beneficial nutrients have RDAs or Upper Levels (ULs). There are numerous substances that are nutritionally beneficial that have neither an RDA nor a UL. In addition, the National Academy of Sciences' Food and Nutrition Board has applied different standards over time in identifying beneficial nutrients.

Setting the "no exposure" level in foods at 20% of the Upper Level is arbitrary and scientifically inappropriate. In most cases, the UL is not based on either cancer or reproductive endpoint. In effect, the Proposal regulates substances on the basis of toxic effects and endpoints which are outside the scope of Proposition 65. In effect, the Proposal would have the effect of expanding Proposition 65 beyond the scope of the statute since it would set limits on the basis of endpoints not intended to be regulated by Proposition 65.

In the case of some beneficial nutrients, 20% of the UL is higher than the RDA. In other cases, the reverse is true, i.e., the RDA is higher than 20% of the UL. Some beneficial nutrients would be effectively "penalized" by virtue of having an RDA because the

trigger for a Proposition 65 warning would have been higher if it were based on 20% of the UL.

It is not clear how the Proposal would be applied when the RDA or UL varies by age group, which is often the case. For example, if the UL varies by age group, how would the Proposal work? Would it be necessary to conduct studies to determine the age group of the average consumer of each product?

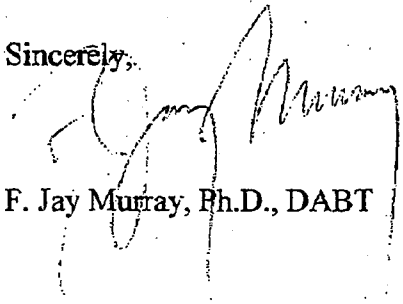
Some beneficial nutrients do have neither an RDA nor a UL for certain age groups. For example, no RDA or UL exists for infants (0-12 months of age) for certain beneficial nutrients. In such a case, it might be necessary to provide a "cancer or birth defects" warning for beneficial nutrients in foods intended for infants (e.g., milk, formula, baby foods), but not for other foods containing larger amounts of the same beneficial nutrient. Alternatively, the UL for adults or children might be assumed to apply since there is no UL for infants. The Proposal is ambiguous about how this might work.

Conclusions

In conclusion, OEHHA should discontinue its regulatory reform efforts to exempt exposure to certain beneficial nutrients in food products when exposure is below the RDA or 20% of the UL. The Proposal provides no benefit to public health or to the food industry. Further, the Proposal should not tie an exemption to the RDA or the UL for the reasons described herein.

Thank for the opportunity to provide these comments. If you have any questions, please feel free to contact me at 408-239-0669.

Sincerely,



F. Jay Murray, Ph.D., DABT

cc: Dr. Joan Denton
Mr. Allan Hirsch
Ms. Carol Monahan-Cummings